Supreme Court, U.S.
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No. OFFICE OF THE CLERK

In The

Supreme Court of the United States

October Term, 1996

IRENE M. GREEN and MARTIN GREEN,

Petitioners,

v.

RICHARD L. DOLSKY, M.D., and
COLLAGEN CORPORATION,

Respondents.

**On Petition For Writ Of Certiorari
To The Supreme Court Of Pennsylvania,
Eastern District**

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Do the Medical Device Amendments of 1976 to the Food, Drug & Cosmetic Act, 21 U.S.C. Section 360c et seq., preempt state tort law claims against a manufacturer and treating physician to recover for injuries caused by a PMA-approved Class III medical device?

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PETITION FOR WRIT OF CERTIORARI

Irene M. Green and Martin Green respectfully petition for a writ of certiorari to review the judgment of the Pennsylvania supreme court in this case.

This Court previously ruled in *Medtronic, Inc. v. Lohr*, 518 U.S. ___, 116 S. Ct. 2240, 1996 U.S. Lexis 4260 (June 26, 1996), that not all state tort law claims are preempted in regards to Class III medical devices, and that as to Class III devices approved for marketing under Section 510(k) of the MDA, design claims specifically would not be preempted. While *Lohr* involved a Class III "grandfathered" device under section 510(k) and Petitioners' claims here involve a Class III PMA device, to a significant degree the Court's reasoning in *Lohr* would equally apply to preclude preemption of claims regarding Class III PMA-approved devices.[1] The actual question, however, was not specifically addressed in *Lohr*, nor did *Lohr* consider whether the MDA preempts a *treating physician's* common law liability to his patient. For these and other

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[1] Indeed, the Court granted, vacated and remanded several pending Class III device preemption petitions for reconsideration in light of *Lohr*, including IDE, Section 510(k) and PMA devices: *see Duvall v. Bristol-Myers-Squibb*, No. 95-1010; *English v. Mentor*, No. 95-1034, and *Mentor v. Feldt*, No. 95-1214, (involving Sec. 510(k) devices); *Mitchell v. Collagen Corporation*, No. 95-1323, (involving a PMA-approved device); *Martin v. Telectronics Pacing Systems, Inc.*, 116 S. Ct. 2576 (1996) (involving an IDE-device.)

The Court, however, denied review in *Kennedy v. Collagen Corporation*, No. 95-1644, which had refused to find preemption of state tort claims regarding the same PMA-approved device as involved herein.

reasons, the Pennsylvania supreme court preempted under the MDA substantially all of Petitioners' state tort law claims.

This issue of *Lohr*'s application to Class III PMA-approved device preemption cases is being acknowledged with uncertainty and inconsistency among the state and federal courts that have addressed it. Moreover, the issue is currently under consideration (or reconsideration) by a number of courts.[2] The issue is ripe for final determination on the merits by this Court.

OPINIONS BELOW

The opinion of the Pennsylvania supreme court, App. at 1-17, is reported at 685 A.2d 110 (1996). The opinion of the Pennsylvania superior court, App. at 18-32, is unreported. The trial court's opinion and order appear at App. 33-35.

[2] *See*, e.g., *Mitchell v. Collagen Corporation*, #94-3946 (remanded by this Court to the Seventh Circuit for reconsideration in light of *Lohr*); *Worthy v. Collagen Corporation*, writ granted, Texas Supreme Court, #96-0675; *Steele v. Collagen Corporation*, California Court of Appeals, Third District, No. 3 Civ C019928; *Mears v. Collagen Corporation*, Arizona supreme court remanded to appellate court for reconsideration in light of *Lohr*, #CA-A85078.

JURISDICTION

The judgment of the Pennsylvania supreme court was entered on November 22, 1996. This Court has jurisdiction under 28 U.S.C. Section 1257.

STATUTES AND REGULATIONS INVOLVED

21 U.S.C. Sec. 360k provides:

(a) General Rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt Requirements

Upon application of a State or a political subdivision hereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if –

(1) the requirement is more stringent than a requirement under this chapter, which would be applicable to the device if an exemption were not in effect under this subdivision; or

(2) the requirement –

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. Sec. 360h(d) provides:

Effect on other liability. Compliance with an order under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

21 C.F.R. Sec. 808.1(d) provides in pertinent part:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section [360k] of the act because they are not "requirements

applicable to a device" within the meaning of section [360k] of the act. The following are examples of State or local requirements that are not regarded as preempted by section [360k] of the act:

> (1) Section [360k] does not preempt state or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranties of fitness), or to unfair practices in which the requirements are not limited to devices . . .

STATEMENT OF THE CASE

Irene and Martin Green brought state law strict liability, negligence, warranty, fraud, deceptive acts, mislabeling, misbranding and adulterated device claims against Collagen Corporation, and negligence claims against the injecting physician, seeking damages for injuries caused to Irene Green by injections with Collagen Corporation's Class III PMA-device, Zyderm. The Pennsylvania state trial court granted summary judgment in favor of both defendants, holding that the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act ("MDA") preempted all of the Petitioners' claims. On appeal, the Pennsylvania superior court affirmed the decision. The Pennsylvania supreme court substantially affirmed the lower court decisions, and held that the MDA preempted Petitioners' claims regarding device design, warning and labeling, strict liability, breach of

warranty against Collagen Corporation, and certain medical malpractice and negligence claims against the injecting physician.

The basic structure of the MDA, insofar as it applies to PMA-devices, is described in Part A below. Part B considers the underlying facts and proceedings before the Pennsylvania Supreme Court and lower courts.

A. The Basic Structure of the Medical Device Amendments of 1976 regarding PMA-devices

As the basic tenets and history of the MDA were thoroughly reviewed and analyzed by this Court in the *Lohr* decision, only the specific attributes of Class III PMA-medical devices under the MDA will be discussed.

In contrast to the "grandfathered" Section 510(k) marketing-approval process utilized by the Class III device in *Lohr*, the Class III device here was approved through the pre-market application approval process ("PMA") of 21 U.S.C. Section 360e(d)(2).[3] Zyderm, the device which injured Irene Green, was granted marketing approval in 1981 prior to the FDA's promulgation of the MDA regulations.

The PMA-approval process under the MDA is no more device-specific (or less general) than the Section 510(k) process. Both are generalized procedures for marketing Class III devices, and are subject to the same

---

[3] While the 1976 MDA required the FDA to promulgate regulations to effectuate the MDA, these regulations were not promulgated until 1986.

manufacturing, labeling and warning regulations. The primary distinction is that the PMA-devices must submit and obtain approval of a pre-marketing application, which is reviewed by the FDA and either approved for marketing, rejected, or sent back for submission of further information. As with any other Class III device, the FDA does not undertake independent clinical or laboratory testing of the proposed device, and relies strictly on the data and information submitted by the manufacturer in the PMA.

The MDA preemption provision of Section 360k does not distinguish among the various types of marketing approval, and applies equally to all Class III devices, whether IDE, PMA or "grandfathered."

B. Facts and Lower Court Proceedings

Irene Green received injections of Collagen Corporation's Zyderm device in 1989. Zyderm is a processed cow protein material marketed by Collagen Corporation for injection into soft tissues such as the face. The injections were administered by Respondent Richard L. Dolsky, M.D. Following her injections, Petitioner Irene Green developed a serious medical condition known as "aplastic anemia," which required continuous hospitalizations and aggressive drug therapy.

Suit was filed in 1992 against Collagen Corporation and the injecting physician, claiming damages under strict liability, defective design, defective manufacturing, failure to warn; negligence in design and manufacturing; breach of warranties; fraud, misrepresentation and

deceptive acts, mislabeling, misbranding and adulterated device, and medical negligence.

Respondents filed for summary judgment, alleging that Section 360k(a) of the MDA preempted all of Petitioners' state law claims. Summary judgment based on MDA preemption was granted in favor of both defendants. App. at 35.

The superior court of Pennsylvania affirmed, substantially relying on the Pennsylvania federal district court's decision in *Michael v. Shiley*, ___ F.Supp. ___, which was later partially overruled by the Third Circuit. *Id.* at 46 F.3d 1316 (3rd Cir.), cert. denied, 116 S. Ct. 67 (1995).

The supreme court of Pennsylvania substantially affirmed the lower preemption rulings, allowing to stand only a few, narrowly-drawn state law negligence claims against the manufacturer and injecting physician.

REASONS FOR GRANTING THE PETITION

A. THE PENNSYLVANIA SUPREME COURT'S DECISION CONFLICTS WITH THIS COURT'S DECISION IN *LOHR* REGARDING PREEMPTION OF MEDICAL DEVICE CLAIMS.

The Supreme Court's recent decision in *Lohr v. Medtronic* significantly controls the question of MDA preemption as to a Class III medical device manufacturer's liability, and would appear to do so without overt regard as to the manner in which FDA marketing clearance was obtained. Moreover, nothing within the MDA or *Lohr*

would justify or support the use of Section 360k to defeat common law negligence claims against a physician.

Only in regards to design defect claims did the Court in *Lohr* appear to narrow the analysis specifically to the Section 510(k) marketing process; the remainder of the opinion reviews the MDA and Section 360k preemption without apparent limitation to any particular Class III marketing clearance procedure. The concerns expressed by the Court against preemption appear to focus on overall policy considerations applicable to *all* Class III devices under the MDA.

The Court in *Lohr* held against preemption of labeling, manufacturing and warning claims, as (a) such state tort law claims are general state law requirements not specifically developed with respect to medical devices, and (b) the federal labeling, warning and manufacturing requirements are entirely generic concerns about device regulation generally, not a specific regulation. 1996 WL 345808, *15. As stated by this Court,

> Nothing in section 360k denies [the State] the right to provide a traditional damages remedy for violation of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of [State] law to provide that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirements.

Id. For the same reasons that the Lohrs' claims were not preempted, Petitioners' claims should not be preempted:

> The legal duty that is the predicate for the Lohr's negligent manufacturing claim is the general duty of every manufacturer to use care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use . . . These state requirements therefore escape preemption, not because of the source of the duty is a judge-made common law rule, but because their generality leaves them outside the category of requirements that Section 360k envisioned to be "with respect to" specific devices as pacemakers.

Id. at *18. Particularly, in regards to the Court's acknowledgement that device-specific regulations are a prerequisite to preemption, the Court stated that

> [G]iven the critical importance of device-specificity in our (and the FDA's) construction of Sec. 360k, it is apparent that few, if any, common-law duties have been preempted by [the MDA]. It will be rare indeed for a court hearing a common-law cause of action to issue a decree that has "the effect of establishing a substantive requirement for a specific device."

Id. *15. The Court further stated in regards to device-specificity prerequisites that

> The requirements identified [by the lower court] include labeling regulations *which require manufacturers of every medical device,* with a few limiting exceptions, to include with the device a label

> containing "information for use . . . and any relevant hazards, contraindications, side effects and precautions." Similarly, manufacturers are required to comply with "Good Manufacturing Practices," or GMPs . . .

Id. at *13-*14. (emphasis added) Those provisions of the MDA relied upon by the Court throughout *Lohr* apply independently to all Class III devices, without regard to PMA or Section 510(k) status. *Lohr* does not appear to distinguish between labeling and warning claims arising from PMA as opposed to Section 510(k) devices, and strongly suggests that such a distinction should not be drawn.

For the same reasons that Section 510(k) was rejected by this Court as a "specific requirement," the PMA process would not stand as a "specific requirement":

> Lohrs' common-law claims are not preempted by the federal labeling and manufacturing requirements . . . Rather, the federal requirements reflect entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulations which the statute or regulations were designed to protect from potentially contradictory state requirements.

Id. at *18.

The Pennsylvania supreme court, in preempting Petitioners' labeling, manufacturing and warning claims, contravened the clear language and holding of the Court in *Lohr.*

In upholding preemption of Petitioners' breach of warranty claims, the Pennsylvania supreme court stated that "With respect to the breach of warranty claim that

'Zyderm as safe, fit and proper for cosmetic use for injection into the body,' the claim must fail for the FDA has restricted the labeling to be used in the sale of this product." This is circuitous, analysis, akin to holding that "There was no misrepresentation, because the FDA prohibits misrepresentation," and runs far afield of *Lohr.*

The remainder of Petitioners' claims as preempted by the Pennsylvania supreme court would not be preempted by *Lohr,* inasmuch as such claims hold Respondent manufacturer to the same standard and requirements as it must meet under FDA requirements. The MDA mandates the marketing of reasonably safe and effective medical devices, and the manufacturer, under FDA requirements, must show the device to be reasonably safe and effective. Thus, any requirement that Zyderm be reasonably safe would merely parallel the FDA's own regime, and not be preempted.

Contrary to the Pennsylvania supreme court's statements, any finding of strict liability on the part of Collagen Corporation would *not* be problematic in light of the FDA's earlier finding of reasonable safety and effectiveness. Section 360k does not concern itself with FDA *findings,* but rather with *requirements.* Zyderm is required to be reasonably safe and effective; any state law claim requiring or enforcing the same standard would parallel, not contravene, the MDA standards. Any hypothetical jury finding that Zyderm is not reasonably safe under the facts and circumstances of a particular case would be a finding limited to the facts of that case, and not stand as a generalized safety finding on par with or in derogation of the earlier FDA administrative determination.

Moreover, there is no authority for the Pennsylvania supreme court's preemption under the MDA of claims against an injecting physician for state law malpractice and negligence.

B. THE PENNSYLVANIA SUPREME COURT'S DECISION CONFLICTS WITH OTHER DECISIONS REGARDING PREEMPTION OF MEDICAL DEVICE CLAIMS

In preempting substantially all of Petitioners' state tort law claims, the Pennsylvania supreme court is in conflict with several recent post *Lohr* decisions on the issue:

> *Fiore v. Collagen Corporation*, Arizona Court of Appeals (June 25, 1996), reversing preemption of state tort laws claims against Collagen Corporation regarding Zyderm, the same medical device and manufacturer as involved here. The Arizona Supreme Court refused review of the decision, January 14, 1997.
>
> *Kernats v. Smith Ind. Med. Systems, Inc.*, 669 N.E. 2d 1300 (Ill. App. 1996), holding that no state tort law claims are preempted against the manufacturer of a PMA-approved Class III device, as such common law duties are of "general applicability" which are not preempted under *Lohr*.
>
> *Armstrong v. Optical Radiation Corp.*, 1996 WL 625305, 1996, ruling that no state tort law claims are preempted against the manufacturer of a Class III PMA-approved device, as such state law duties are those of "general applicability" and were not preempted under *Lohr*.

Committee of Dental Amalgam Manufacturers and Distributors v. Stratton, 92 F.3d 807 (9th Cir. 1996), deciding that neither the FDA's manufacturing and labeling rules nor California's warning requirements are "specific" enough to warrant preemption under *Lohr*.

Mears v. Collagen Corporation, Oregon supreme court, #CA-A85078 (8/28/96). The supreme court reversed the appellate court's preemption of appellant's state law claims, and remanded for reconsideration in light of *Lohr*.

Walker v. Johnson and Johnson Vision Products, Inc., 522 N.W.2d 679 (Mich. App. 1996), holding that no product liability claims for Class III PMA devices are preempted. The opinion was prepared prior to *Lohr*, but explains that its holding is fully consistent with *Lohr*; a concurring opinion relies in its entirety on *Lohr*.

C. TO THE EXTENT THAT *LOHR* ENTIRELY CONTROLS THIS CASE, PETITIONERS' APPEAL CAN BE SUMMARILY DISPOSED OF UNDER SUPREME COURT RULE 16.1.

Under Rule 16.1, Rules of the Supreme Court of the United States, a petition for writ of certiorari "may be a summary disposition on the merits." In the past, the Court has primarily utilized this Rule to summarily reverse cases in light of an existing, controlling Supreme Court case precedent on the merits. *See*, e.g., *Redrup v. New York*, 386 U.S. 767 (1967).

Should it be this Court's opinion that *Lohr* fully controls the issues and disposition of this appeal, Petitioners respectfully request that the Court summarily reverse the

lower court decision, noting that the case is controlled by *Lohr.*

D. RESOLUTION OF THE MEDICAL DEVICE PREEMPTION ISSUE REGARDING PMA-APPROVED MEDICAL DEVICES IS IMPORTANT.

While *Lohr* may very well control the question of MDA preemption for PMA-approved Class III medical devices, courts throughout the various jurisdictions are not in agreement, resulting in inconsistent interpretation and application of the MDA preemption. For example, this Court reversed and remanded the Sixth Circuit's preemption decision in *Martin v. Telectronics Pacing Systems, Inc.,* for reconsideration in light of *Lohr.* On January 31, 1997, the Sixth Circuit issued its new opinion, fully affirming its own earlier opinion. The Sixth Circuit held that all claims were preempted regarding a Class III IDE device, and basically stated that *Lohr* was limited to Section 510(k) "grandfathered" Class III devices. 1997 WL 35041.

Furthermore, in the decision of *Berish v. Richards Medical Co.,* ___ F. Supp. ___ (N.D.N.Y.), 1996 WL 481556 (8/22/96), the federal court, upon reconsideration in light of *Lohr,* refused to change its prior holding that negligence and strict liability claims regarding an investigational device are preempted, but did partially reverse its prior decision to hold that claims alleging violations of applicable federal regulations are not preempted.

To the extent that *Lohr* does resolve the question, such must be made clear to the growing number of courts

in disagreement with *Lohr's* applicability. Without focused guidance from this Court, the interpretation of federal MDA preemption will continue to wander down its currently haphazard path, without consistency or uniformity.

To the extent that *Lohr* does **not** determine the question, the issue of MDA preemption of Class III PMA-approved medical devices needs speedy resolution by the Court, as it has become, and will continue to be, an incongruous, inconsistent area of federal law in absence of further clarification and guidance by this Court.

CONCLUSION

Petitioners Irene M. Green and Martin Green respectfully request that this petition for writ of certiorari be granted.

Respectfully submitted,

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[J-168-1995]

IN THE SUPREME COURT OF PENNSYLVANIA
EASTERN DISTRICT

IRENE M. GREEN and MARTIN GREEN,	:	No. 104 E.D. Appeal Docket 1994
Appellants	:	Appeal from the Order of the Superior Court of Pennsylvania, dated May 10, 1994, at No. 2974 Philadelphia 1993, affirming the Order of the Court of Common Pleas of Montgomery County, Pennsylvania, Civil No. 92-07089, entered September 3, 1993
v.	:	
RICHARD L. DOLSKY, M.D. and COLLAGEN CORPORATION,	:	
Appellees	:	
	:	433 Pa.Super. 556, 641 A.2d 600 (1994)
	:	ARGUED: October 24, 1995

OPINION ANNOUNCING THE JUDGMENT OF THE COURT

MR. CHIEF JUSTICE FLAHERTY DECIDED: November 22, 1996

The sole question presented in this case is whether section 360k(a) of the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act (FDCA), 21

U.S.C. § 360k(a) (1988) preempts state causes of action sounding in tort.[1]

The relevant facts are that Irene Green allegedly developed an autoimmune disorder after receiving an injection of Zyderm Collagen Implant (Zyderm) from her physician, Dr. Richard Dolsky. Zyderm is manufactured by Collagen Corporation, and is a Class III medical device subject to regulation under the MDA before it may be sold to the public. 21 U.S.C. § 360c(a)(1)(C). Zyderm has been on the market since 1981, when FDA approved Collagen's application to sell it. FDA reaffirmed that approval in 1992.

In 1992, Mrs. Green and her husband sued Dr. Dolsky on the theories of negligence, failure to warn and failure to obtain informed consent. She and her husband also sued Collagen on the theories of negligence, strict liability, and breach of warranty. Green's husband sought damages from both defendants for loss of consortium. The trial court held that the MDA preempted these claims and granted summary judgment for the defendants. Superior Court affirmed and we granted Green's petition for allowance of appeal.

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[1] Section 360k(a) of the MDA to the FDCA provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this Act to the device and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

21 U.S.C. § 360k(a).

THE REGULATORY SCHEME

The United States Court of Appeals for the Eleventh Circuit recently provided the following overview of the history and purpose of the regulatory scheme of which the MDA are a part:

> The market for medical devices was largely unregulated at the national level until the MDA's passage in 1976. With the MDA, Congress gave the federal Food and Drug Administration (FDA) comprehensive jurisdiction over all "devices intended for human use." 21 U.S.C.A. § 360c(a)(1). The text of the MDA reveals two competing congressional purposes relevant to this case: (1) the MDA protects the public from unnecessary illness or injury by subjecting medical devices to a regulatory scheme designed to ensure that the devices are safe and effective, *see, e.g.*, 21 U.S.C.A. §§ 360c(a)(1)(A)(i); 360c(a)(1)(B); 360e(d)(2); and (2) the MDA protects the public by encouraging the development and marketing of medical devices by crafting a nationally uniform regulatory scheme that prevents overregulation and thus ensures that development can be economically feasible . . .

Lohr v. Medtronic, Inc., 56 F.3d 1335, 1339 (11th Cir. 1995) (footnote omitted).

The MDA were enacted in response to public dissatisfaction following injuries in the 1960's and 1970's by women using the Dalkon Shield, a contraceptive device. Although the Dalkon Shield was marketed as a safe and effective contraceptive device, its use resulted in a high number of unintended pregnancies, infections, and even

in a few cases, death. *Medtronic v. Lohr*, 518 U.S. ___ (1996) (Slip Op. at 3). It was apparent that the pace of development in the medical device industry exceeded any existing governmental controls, and the MDA, which give the FDA broad powers to regulate medical devices, were enacted as a remedy. See *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995).

The MDA classifies medical devices as Class I, II or III, depending upon their potential danger to the public. Class I devices pose little or no threat to health and safety and are subject to only general controls over manufacturing. 21 U.S.C. § 360c(a)(1)(A). Examples of Class I devices are elastic bandages, tongue depressors and bed pans. Class II devices require special controls, such as performance standards, postmarket surveillance, patient registries and guidelines for use of the devices. 21 U.S.C. § 360(c)(a)(1)(B). Examples of Class II devices are oxygen masks, tampons, syringes, hearing aids, and condoms. Class III devices are "for use in supporting or sustaining human life or . . . of substantial importance in preventing impairment of human health" or "present a potential unreasonable risk of illness of injury." 21 U.S.C. § 360c(a)(1)(C). Class III devices include replacement joints, pacemakers and heart valves. Thus, Class III devices are the most heavily regulated. Included in this class is the Zyderm which was implanted in Mrs. Green.

There are two methods of securing approval to sell a Class III device. The first is the premarket approval process, in which the manufacturer must submit a detailed premarket approval application to the FDA that presents all available information concerning investigations of the device's safety and effectiveness; detailed information

regarding its design, components, ingredients, properties, and principles of its operation; a full description of manufacturing methods and controls. 21 U.S.C. § 360e(c)(1). This premarket application must be approved before the device can be sold. 21 U.S.C. § 360c(a)(1)(C).

After premarket approval has been given, the FDA may, under certain conditions, withdraw approval, and it also has other powers:

> The FDA has limited remedial power to require the manufacturer to notify the public of newly discovered risks; to order repair, replacement or refund of the purchase price of a device; and to order recall of a device. [21 U.S.C.] at § 360h. Additionally, a device manufacturer is subject to criminal penalties for certain prohibited acts and may be assessed civil penalties by the FDA. [21 U.S.C.] at §§331, 333. It is generally understood . . . that there is no private right of action under the Food, Drug and Cosmetics Act. *See Talbott v. C.R. Bard, Inc.*, 865 F.Supp 37, 45 (D. Mass. 1994) . . . *see also King v. Collagen Corp.*, 983 F.2d 1130, 1140 (1st Cir.), *cert. den.* ___ U.S. ___, 114 S. Ct. 84 (1993) (no implied right of action).

Mears v. Marshall and Collagen Corp., 138 Ore App. 476, 909 P2d 212 (1996).

The second method of approval for the sale of a Class III Medical Device is to establish that it is substantially equivalent to a device that is already on the market. See 21 U.S.C. §360e(b)(1)(A). If this can be established, the premarket approval process, which is somewhat lengthy, can be avoided. The rationale for this exception to the premarket approval process is explained by the *Lohr* Court:

> Not all, nor even most, Class III devices on the market today have received premarket approval because of two important exceptions to the PMA requirement. First, Congress realized that existing medical devices could not be withdrawn from the market while the FDA completed its PMA analysis for those devices. The statute therefore includes a "grandfathering" provision which allows pre-1976 devices to remain on the market without FDA approval until such time as the FDA initiates and completes the requisite PMA. . . . Second, to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market, the Act also permits devices that are "substantially equivalent" to pre-existing devices to avoid the PMA process.

Medtronic, Inc. v. Lohr, 518 U.S. ___ (Slip Op. at 4-5).

PREEMPTION

The United States Supreme Court has discussed preemption as follows:

> Article VI of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." Art VI, cl 2. Thus, since our decision in McCulloch v. Maryland, 4 Wheat 316, 427, 4 LEd 579 (1819), it has been settled that state law that conflicts with federal law is "without effect." . . . Consideration of issues arising under the Supremacy Clause "start[s] with the assumption that the historic police

> powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." Rice v. Santa Fe Elevator Corp., 331 US 218, 230, 91 LEd 1447, 67 S Ct 1146 (1947). Accordingly, " '[t]he purpose of Congress is the ultimate touchstone' " of pre-emption analysis.

Cipollone v. Liggett Group, Inc., 505 U.S. 504, 112 S.Ct. 2608, ___, 120 L.Ed.2d 407, 422 (1992) (Mr. Justice Stevens, joined in this part of the opinion by Mr. Chief Justice Rehnquist, Messrs. Justice White, Blackmun, Kennedy, and Souter and Madame Justice O'Connor.) Accord, *Medtronic v. Lohr*, 518 U.S. at ___, Slip Op. at 12-13.

DISCUSSION

With this background, we now turn to a discussion of whether the MDA preempt state law causes of action for injuries allegedly received because of the use of a medical device. We note initially that the question arises because, as mentioned earlier, there is no private right of action under the MDA, and in the absence of state law claims, a party injured by a medical device would have no cause of action against any person or entity.

Very recently the Supreme Court of the United States has resolved at least some of the questions involved in this case. In *Medtronic v. Lohr*, 518 U.S. ___ (June 26, 1996), the Lohrs brought a state court action in negligence and strict liability, claiming that a pacemaker manufactured by Medtronic had failed, injuring Mrs. Lohr. The pacemaker was a Class III device under the MDA, and it had been approved for sale under that portion of the MDA which allowed for sale of the device without premarket

approval if the device was "substantially equivalent" to devices which were already on the market. See 21 U.S.C. §360e(b)(1)(A). This method of approval is known as the §510(k) process after the number of the section in the original act.[2]

Mr. Justice Stevens, joined by Messrs. Justice Kennedy, Souter and Ginsburg, announced the judgment of the Court in *Lohr*. Mr. Justice Breyer joined the opinion except for two sections and concurred in the judgment. The majority held that Lohrs' design claim was not preempted, for the device had been approved for sale under the §510(k) provision, which meant that the FDA had not examined the merits or safety of this particular device, but had decided only that it was substantially equivalent to devices already on the market. 518 U.S. at ___, Slip Op. at 22.

Further, the Court held that state claims alleging the manufacturer violated FDA regulations can be maintained, and that even if state causes of action require the proof of negligence or the creation of an unreasonable hazard, such additional elements make the claim narrower, not broader, and thus, are not to be regarded as additional or different "requirements." 518 U.S. at ___, Slip Op. at 23.[3]

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[2] In 1990, a committee of the House of Representatives reported that 80% of new Class III medical devices were introduced to the market by way of the §510(k) process. *Lohr* at 6-7 (Slip Op.)

[3] The Court stated:

> The regulations promulgated by the FDA expressly support the conclusion that §360(k) "does

Additionally, the Court concluded that the Lohr's manufacturing and labeling claims are not preempted by the Act, for the regulations in *Lohr* concerned device regulation generally, and not a specific device or field of device regulation which might be contradicted by state requirements. The Court pointed out that whether manufacturing and labeling claims are preempted will "require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement. . . . " 518 U.S. at ___, Slip Op. at 29.

Four justices, (Madame Justice O'Connor, joined by the Chief Justice, and Messrs. Justice Scalia and Thomas) concurring in part and dissenting in part, agreed with the majority that Lohrs' defective design claim was not preempted because the §510(k) process merely confirms that pre-1976 and post-1976 devices are equivalent: it does not impose "requirements." These justices also agreed that the Lohr's claims were not preempted insofar as they seek to enforce FDA requirements, for such claims do not impose requirements that are different from or in addition to requirements under federal law.

The four justices dissented, however, to the majority's view that §360k does not preempt state common law actions. In the view of the dissenters, if the common law action imposed any requirement different from FDA requirements, it should be preempted. The dissenters also

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not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." 21 CFR §808.1(d)(2) (1995).

Slip Op. at 25.

disagreed that the Lohrs' manufacturing and labeling claims would survive preemption, for the FDA's good manufacturing practice regulations, in the view of the dissent, imposed comprehensive requirements which were different from the negligence standard which would be alleged in common law claims regarding manufacturing. Similarly, the dissenters would disallow the failure to warn claim because they regarded it as preempted by the federal labeling requirements.

Mr. Justice Breyer concurred in part and concurred in the judgment. Justice Breyer would hold that the MDA preempt a state law tort suit when the standard of care or behavior imposed by the lawsuit would be preempted if it were a state regulation instead of an element in a common law cause of action. He also observed that ordinary principles of preemption should control: viz., the state requirements actually conflict with the federal requirements, or the scheme of federal regulation is so pervasive as to compel the conclusion that there is no room for the states to supplement it, 518 U.S. at ___, Slip Op. at 6 (Concurring Op).

Although *Lohr* answers some questions raised in this case, it is not wholly applicable, for in *Lohr* the §510(k) process was utilized to market the device, and in the present case, the premarket approval process was utilized. Nonetheless, some guidance is available. First, *Lohr* teaches that state claims which allege that FDA requirements have not been met are cognizable. Second, if a state cause of action requires proof of additional elements such as negligence or creation of a hazard, these elements are not additional "requirements" within the meaning of §360(k). Third, manufacturing and labeling claims will

not be preempted so long as the federal requirements do not relate to the specific device at issue.

In the case at bar, the FDA approved Zyderm for sale in the form submitted to the agency, and required, as a condition of its approval, that any changes that might adversely affect the safety or effectiveness of the device must first receive agency approval, including but not limited to the following:

> (1) New indications for use; (2) labeling changes; (3) changes in manufacturing facilities, methods or quality control procedures; (4) changes in sterilization procedures; (5) changes in packaging; and (5) changes in performance or design specifications.

R.R. 452b-456b. 21 C.F.R. §808.1(d) provides:

> State or local requirements are preempted only where the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act.

Pursuant to these considerations, the following negligence claims with respect to the Collagen Corporation are preempted, since the FDA preempted the field of regulation by issuing specific regulations with respect to the claims asserted:

a. negligent development of the product[4]

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[4] The claims stated in the complaint are not repeated here verbatim, but are stated in abbreviated form. The letters identifying each claim correspond to the letters used in the First Amended Complaint.

b. failing to warn plaintiff[5]

d. failing to give adequate warning to physicians[6]

n. failing to properly label the product

These claims are impermissible because they attempt to substitute a reasonableness analysis characteristic of negligence claims for the judgment of the FDA in approving the development and distribution of this particular product in the course of its premarket approval process.

The following negligence claims are so general as to preclude our determination as to preemption:

p. being negligent as a matter of law.

q. being otherwise negligent, careless or reckless

r. violating the statutes, laws or regulations of the United States and Pennsylvania.

The following negligence claims, which, in essence, mirror FDA requirements, are not preempted:

c. negligent distribution of Zyderm in commerce, knowing Zyderm to be defective and dangerous.[7]

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[5] As indicated above, the FDA approved the labeling and package inserts which would accompany the product.

[6] The FDA approved the Physician Package Insert, which was, in effect, instruction to physicians for use of the product. Letter of February 3, 1982 from Debera Brown to Thomas J. Callahan of the FDA.

[7] Several of Green's negligence allegations include the phrase "known or knowable." We approve the cause of action

e. allowing Zyderm to be sold in the face of known consequences

f. failing to test adequately, in the face of known consequences.

g. failing to provide FDA with all data

h. failing to provide FDA with known product risks and reactions

i. failing to adequately study adverse reactions, in the face of known consequences.

j. allowing Zyderm to be sold while knowing of dangerous propensities

k. providing FDA with false, fraudulent, incomplete testing results

l. providing FDA with false, fraudulent, incomplete adverse reaction or injury information

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insofar as it concerns that which was known, but not as to that which was knowable. If the manufacturer sold, distributed, failed to test, failed to study adverse reactions of the product, knowing that the product was defective, the allegations are, in essence, that the manufacturer fraudulently completed the premarket approval process. Such claims are cognizable for they mirror FDA prohibitions against fraud.

On the other hand, insofar as Green alleges that certain things were "knowable," such claims are preempted by the premarket approval process. The FDA preempted the field of that which was knowable by determining, after reviewing the premarket approval materials for Zyderm, that the information submitted was sufficient. The plaintiff may not inquire further as to what should have been known, unless the allegation is that the manufacturer was engaged in fraud or deliberate obfuscation in submitting its premarket approval application.

m. failing to withdraw Zyderm from the market under the circumstances

o. failing to properly monitor and identify patients who had been injected with Zyderm after learning of adverse consequences.[8]

Green's strict liability claim is precluded by §360k. The essence of the strict liability claim is that the manufacturer placed a dangerous and defective device into commerce, the product was administered in unchanged condition, and the product caused the injuries alleged. However, this product was approved for sale after undergoing the premarket approval process. In other words, the FDA determined that the product was neither dangerous nor defective. To allow a strict liability claim for a product specifically approved by the FDA would be to impose "requirements" which are different from those of the FDA and which affect the safety of the device, in violation of § 360k.

With respect to the breach of warranty claim that "Zyderm was safe, fit and proper for cosmetic use for injection into the body," the claim must fail for the FDA has restricted the labeling to be used in the sale of this product.

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[8] The July 22, 1981 letter from the Food and Drug Administration approving the premarket approval application for Zyderm contains a requirement for post-approval studies of patients who have received Zyderm treatment. (Def Ex. 4). This claim is permitted insofar as it does not exceed the requirements stated by the FDA. See also, "Conditions of Approval," Adverse Reaction and Device Defect Reporting, R.R. 455b-456b.

With respect to the claims against Dr. Dolsky, the claim that Dolsky was negligent in failing to educate himself and his staff as to the proper means to administer Zyderm; that he did not adequately investigate the side effects of the product; that he failed to maintain proper medical records under the circumstances are all permissible medical malpractice claims.

Likewise, the failure to warn and the failure to obtain informed consent claims are permissible medical malpractice claims. All of the malpractice claims, of course, are circumscribed by the MDA. If Dr. Dolsky read the materials required and/or approved by the FDA for circulation to physicians, he will not be held liable for failure to educate himself or to warn where he followed the instructions contained therein and made known to the patient the risks which were stated in the FDA materials.

Reversed and remanded for further proceedings consistent with this opinion.

Former Chief Justice Nix and Senior Justice Montemuro, sitting at the time of argument, did not participate in the decision of this case.

Mr. Justice Cappy files a concurring opinion which is joined by Mr. Justice Castille.

Judgment entered
Dated: November 22, 1996

/s/ Charles W. Johns
Charles W. Johns, Esquire
Prothonotary

[J-168-1995]
IN THE SUPREME COURT OF PENNSYLVANIA
EASTERN DISTRICT

IRENE M. GREEN and MARTIN GREEN,	:	No. 104 Eastern District
	:	Appeal Docket 1994
Appellants	:	
RICHARD L. DOLSKY, M.D. and COLLAGEN CORPORATION,	:	Appeal from the Order of the Superior Court of Pennsylvania, dated May 10, 1994, at No. 2974 Philadelphia 1993, affirming the Order of the Court of Common Pleas of Montgomery County, Pennsylvania, Civil No. 92-07089, entered September 3, 1993
Appellees	:	
	:	433 Pa.Super. 556, 641 A.2d 600 (1994)
	:	ARGUED: October 24, 1995

CONCURRING OPINION

MR. JUSTICE CAPPY: DECIDED: November 22, 1996

I am in accord with the result reached by the majority. I write separately, however, to express my disagreement with the majority's statement that "[a]ll of the [medical] malpractice claims, of course, are circumscribed by the MDA." Majority slip op. at 15.

The MDA preempts a state requirement which "(1) is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates

to the safety or effectiveness of the device . . . ." 21 U.S.C. §360k(a). The United States Supreme Court has held that a statute which preempts "state requirements" could also preempt some common-law tort actions. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992); *Medtronic v. Lohr*, ___U.S.___, 116 S.Ct. 2240, ___ L.Ed.2d ___ (1996).

Yet, for a common-law tort action to be preempted by the MDA, it must impose requirements *on the device. See* 21 U.S.C. §360(k)(a). Medical malpractice law simply does not place requirements on a device. Such law establishes requirements for the professional standard of care required of our medical community. Even where the allegation is that a physician committed malpractice while employing a medical device in his treatment, the issue to be resolved – and the law created by that resolution – concerns whether the physician's conduct was reasonable. Resolution of that issue does not create standards concerning the safety and efficaciousness of the product in question.

For the foregoing reasons, I am unable to join that portion of the majority's opinion which concludes that the preemption provision of the MDA applies to medical malpractice claims.

Mr. Justice Castille joins this concurring opinion.

J. A10004/94

IRENE M. GREEN and MARTIN GREEN, Appellants v. RICHARD L. DOLSKY, M.D. and COLLAGEN CORPORATION	:	IN THE SUPERIOR COURT OF PENNSYLVANIA No. 2974 Philadelphia, 1993

Appeal from the Order entered September 3, 1993, Court of Common Pleas, Montgomery County, Civil Division at No. 92-07089.

BEFORE: CIRILLO, BECK AND JOHNSON, JJ.

OPINION BY JOHNSON, J.: FILED MAY 10, 1994

In this case of first impression; we are asked to determine whether the Medical Device Amendments of 1976 (MDA) 21 U.S.C. §§ 360c *et seq.*, 360k, to the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), 21 U.S.C. §§ 513 *et seq.*, 521(a), preempt state tort law claims involving Class III medical devices. Irene M. Green and Martin Green, her husband, appeal from the grant of summary judgment by the Court of Common Pleas of Montgomery County, in favor of Richard L. Dolsky, M.D., and Collagen Corporation (Collagen). Because we find no error of law in the trial court's grant of summary judgment on the basis of federal preemption, we affirm.

Irene Green developed an auto-immune disease after being treated with Zyderm Collagen Implant (Zyderm). Zyderm, which is manufactured by Collagen, is administered by sub-cutaneous injections to improve soft tissue

deficiencies, and it is regulated under the MDA. The Federal Food and Drug Administration (FDA) has classified Zyderm as a Class III medical device that must be approved by the FDA prior to marketing. In July 1981, the FDA issued an order granting Collagen permission to market Zyderm. In 1992, the FDA reaffirmed that order.

Green filed suit against Collagen upon the theories of negligence, strict liability, breach of warranty, and fraud in obtaining FDA approval to market Zyderm. Green also sought punitive damages from Collagen. In addition, Green sued Dr. Dolsky upon the theories of negligence, failure to warn and failure to obtain informed consent. Green's husband joined the action seeking damages from both Collagen and Dr. Dolsky for loss of consortium.

Collagen filed a motion for summary judgment on the basis that the MDA expressly preempt all of the Greens' state tort law claims. Following oral arguments, the trial court granted Collagen's motion for summary judgment. The Greens now appeal.

The sole issue on appeal is whether the trial court erred in granting summary judgment in favor of Collagen on the basis that the MDA preempted the Greens' state tort law claims.

We review a trial court's grant of summary judgment under the following standard:

> Summary judgment shall be entered:
>
> > . . . if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that

> the moving party is entitled to a judgment as a matter of law.
>
> Pa.R.C.P. 1035 (b). "The record must be viewed in the light most favorable to the nonmoving party, and all doubts as to the existence of a genuine issue of material fact must be resolved against the moving party." *Marks v. Tasman*, 527 Pa. 132, [135], 589 A.2d 205, 206 (1991). Summary judgment may be entered only in cases where the right is clear and free from doubt. *Musser v. Vilsmeier Auction Co., Inc.*, 522 Pa. 367, 369, 562 A.2d 279, 280 (1989).

Hayward v. Medical Center, 530 Pa. 320, 324, 608 A.2d 1040, 1042 (1992). *See also Myszkowski v. Penn Stroud Hotel, Inc.*, ___ Pa.Super. ___, ___, 634 A.2d 622, 625 (1993). A trial court's grant of summary judgment will only be reversed for an error of law or a clear abuse of discretion. *Myszkowksi*, at ___, 634 A.2d at 625.

Preliminarily, we note that neither our supreme court, nor this Court, nor the Third Circuit Court of Appeals, has addressed the issue of federal preemption of state tort law claims involving Class III medical devices which have received pre-market approval by the FDA. Recently, however, the United States District Court for the Eastern District of Pennsylvania addressed this issue, and held that the MDA wholly preempt a plaintiff's state tort law claims in cases involving Class III medical devices which have received pre-market approval. *Michael v. Shiley, Inc., et al.*, ___ F.Supp. ___, No. 93-1729 (E.D. Pa. February 25, 1994). "While decisions of the lower federal courts have a persuasive authority, they are not binding on Pennsylvania courts even where they concern federal questions." *Commonwealth v. Giffin*, 407

Pa. Super. 15, 26, 595 A.2d 101, 107 (1991), citing *Hangelias v. Dawson*, 158 Pa.Super. 370, 374, 45 A.2d 392, 394 (1946). However, because we find the reasoning of the district court in *Michael* to be persuasive, we find no error of law in the trial court's grant of summary judgment on the basis of federal preemption.

Under the supremacy clause of the United States Constitution, federal law is "the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. As a result, all conflicts between federal and state laws must be resolved in favor of federal law. *Buzzard v. Roadrunner Trucking, Inc.*, 966 F.2d 777 (3d Cir. 1992). In determining whether a conflict between state and federal law exists, a court looks to congressional intent. *FMC Corp. v. Holliday*, 498 U.S. 52, 111 S.Ct. 403, 112 L.Ed.2d 356 (1990), *appeal after remand*, 932 F.2d 959 (1991).

Generally, preemption may be express or implied, and it is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose. *Id.* at ___. 111 S.Ct. at 407, 112 L.Ed.2d at 363. "Congress' enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not preempted." *Cipollone v. Liggett Group, Inc.*, ___ U.S. ___, ___, 112 S.Ct. 2608, 2618, 120 L.Ed.2d 407, 423 (1992) (holding that the Federal Cigarette Labeling and Advertising Act of 1965 and its amendment preempted some but not all of a lung cancer victim's state law tort claims). When Congress is silent on the matter, state law will be preempted

by federal law "when (a) compliance with both state and federal law is impossible or, (b) when state law stands as an impediment to a federal purpose." *Hunsaker v. Surgidev Corp.*, 818 F.Supp. 744, 747 (M.D. Pa. 1992).

Pursuant to the MDA, the FDA classifies all medical devices into one of three categories. 21 U.S.C. § 360(c). Class I devices, such as tongue depressors, present little or no threat to public health and are thus subject to only general controls on manufacturing. 21 U.S.C. § 360(c)(a)(1)(A); *see also Stamps v. Collagen Corp.*, 984 F.2d 1416, 1418 (5th Cir. 1993), *cert. denied*, ___ U.S. ___, 114 S.Ct. 86, 126 L.Ed.2d 54 (1993). Class II devices, such as tampons and oxygen masks used in anesthesiology, pose more of a threat to public health and thus, are subject to more stringent controls. 21 U.S.C. § 360c(a)(1)(B); *Stamps*, 984 F.2d at 1418. Finally, Class III devices, such as Zyderm, are subject to the most extensive controls "to provide reasonable assurance of . . . safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C); *Stamps*, 984 F.2d at 1419. Class III devices must obtain pre-market approval from the FDA because they "present a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a) (1) (C) (ii) (II).

Section 360e of the MDA sets forth the procedures for pre-market approval, and provides, in pertinent part:

§ 360e. Premarket approval

(a) General requirement

A class III device –

(1) which is subject to a regulation promulgated under subsection (b) of this section; or

(2) which is a class III device . . . is required to have . . . an approval under this section of an application for premarket approval.

* * *

(c) Application for premarket approval

(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain –

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly

> burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;
>
> (F) specimens of the labeling proposed to be used for such device; and
>
> (G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require.

21 U.S.C. § 360e(c)(1)(A)-(G).

Thus, the extensive pre-market approval process requires a manufacturer to submit a detailed application to the FDA, including information pertaining to product specifications, intended use, manufacturing methods, and proposed labeling. An appointed panel of experts conducts a comprehensive review of the application and prepares a report and recommendation. 21 U.S.C. § 360e(c)(2). Within six months of receipt of the application, the FDA must either approve the device for sale, or reject it for additional information or testing. 21 U.S.C. § 360e(d). The MDA also impose extensive post-approval regulations to keep the FDA apprised of any new information or safety findings relating to Class III devices. 21 U.S.C. § 360e(e) and § 360i(a). The FDA may withdraw approval of the product permanently, or suspend its approval temporarily if it determines that the device has become unsafe or its labeling inadequate. 21 U.S.C. § 360e(e).

In enacting the MDA, Congress was not only interested in protecting the individual user, but it was also interested in encouraging research and development and allowing new and improved medical devices to be marketed without delay. *King v. Collagen Corp.*, 983 F.2d 1130, 1138 (1st Cir. 1993), *cert. denied*, ___ U.S. ___, 114 S.Ct. 84, 126 L.Ed 2d 52 (1993). In the MDA, congress included an express preemption provision, 21 U.S.C. § 360k, which provides in pertinent part:

> **§ 360k.** State and local requirements respecting devices
>
> (a) General rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

FDA regulations instruct us that a state requirement within the meaning of section 360k(a) may arise from any requirement established by a state including statutes, regulations, court decisions or ordinances. 21 C.F.R. § 808.1(b). State requirements which, in effect, establish new substantive requirements for a medical device in a regulated area, such as labeling, are preempted. 21 C.F.R.

§ 808.1(d)(6)(ii). Since Congress has provided an express preemption provision in the MDA, we must determine whether the Greens' state law tort claims fall within the scope of that provision by imposing requirements in addition to or different from those mandated by the FDA.

As previously stated, we find the reasoning of the United States District Court for the Eastern District of Pennsylvania in *Michael v. Shiley*, ___ F.Supp. ___, No. 93-1729 (E.D. Pa. February 25, 1994), to be persuasive. In deciding *Michael*, the district court found convincing the well-reasoned analyses of the United States Court of Appeals for the First and Fifth Circuits, in *King v. Collagen Corp., supra*, and *Stamps v. Collagen Corp., supra*, respectively. These Courts of Appeal addressed the issue of whether section 360k of the MDA preempts state tort law claims involving Class III medical devices and both courts answered in the affirmative.

In *Michael*, the plaintiff, Nina Michael, underwent surgery to remove a Bjork-Shiley heart valve prosthesis that had been implanted ten years earlier. Although the prosthesis was functioning properly at the time of explantation, Michael claimed that the removal was necessary because of fear for her safety after hearing reports of incidents of alleged failure or malfunction of Shiley heart valves. Michael sued Shiley, Inc., Hospital Products Group, Inc., and Pfizer, Inc. in the Philadelphia Court of Common Pleas alleging negligence, intentional infliction of emotional distress, strict products liability, breach of express warranty, breach of implied warranty of merchantability, breach of warranty of fitness for a particular purpose, fraud, respondeat superior liability, alter ego liability, and civil conspiracy. Pursuant to 28 U.S.C.

§ 1446, on the basis of diversity of citizenship, the defendants removed the action to the local federal district court.

The defendants filed a motion for summary judgment on all of the above claims. In addition, on the basis of federal preemption pursuant to § 360k(a) of the MDA, the defendants filed a motion for partial summary judgment on Michael's claims of negligence, intentional infliction of emotional distress, strict products liability, breach of implied warranty of merchantability, and fraud. Guided by the analysis in *King, supra,* and *Stamps, supra,* the district court held that the MDA wholly preempt Michael's alleged state law tort claims involving a Class III medical device. *Michael, supra,* slip op. at 36. *See also Hunsaker v. Surgidev, supra,* 818 F.Supp. at 744 (a plaintiff's Pennsylvania tort claims involving intraocular lenses were preempted by the FDCA, the MDA, and the investigational device exemption from the safety and effectiveness requirements of the FDCA and the MDA, 21 C.F.R. §§ 813.1 and 813.5).

In *King v. Collagen Corp., supra,* the plaintiff, Jane King, contracted an auto-immune disease after receiving a test dose of Zyderm. King filed suit against Collagen, the manufacturer, alleging strict liability, breach of warranty of merchantability, negligence, failure to warn, product misbranding/mislabeling, fraudulent misrepresentation, and fraud in obtaining FDA approval. Collagen filed a motion for summary judgment on the basis that the MDA preempted King's claims. The United States District Court for the District of Massachusetts agreed and granted summary judgment.

The First Circuit Court of Appeals affirmed after finding that (1) the extensive pre-market approval process and the similarly extensive post-approval regulations were indications that the FDA had established specific "requirements" within the meaning of § 360k of the MDA and 21 C.F.R. § 808.1(d) of the FDA's regulations, and (2) King's state law tort claims would impose additional or different requirements than those mandated by the FDA, in contravention of § 360k. *King*, 983 F.2d at 1131-32. The court distinguished its result from that reached in *Cipollone v. Liggett Group, Inc., supra,* on the basis that the MDA imposed considerably more extensive regulation on Class III medical devices than the statute requiring cigarette manufacturers to include a brief health warning in their advertisements. *King*, 983 F.2d at 1135.

In *Stamps v. Collagen Corp., supra,* the Fifth Circuit Court of Appeals reached the same result as the First Circuit Court of Appeals in *King*. Jennifer Stamps alleged that she contracted an auto-immune disease after being injected with Zyderm and Zyplast. *Stamps*, 984 F.2d at 1419. Stamps filed suit in a Texas state court against the manufacturer, Collagen, alleging defective design, inadequate warnings and negligent failure to warn. *Id.* at 1418. Collagen removed the action to the local federal district court and filed a motion for summary judgment, which the district court granted on the basis that federal law preempted all of Stamps' state law claims. *Id.* Guided by the express language of § 360k(a), the Fifth Circuit Court of Appeals determined that Stamps' claims were preempted by federal law because first, the state tort law claims would constitute requirements in addition to or

different from the MDA, and, second, these requirements would relate to either the safety or effectiveness of Zyderm and Zyplast. *Id.* at 1422. "State tort causes of action – to the extent they relate to safety, effectiveness, or other MDA requirements – constitute requirements 'different from, or in addition to' the Class III process; they are, therefore, preempted." *Id.* at 1424 (footnote omitted).

In the present case, the Greens claim that the district court erred in granting summary judgment on the basis that the MDA preempted their state tort law claims. Here, we are constrained to agree with the rationale in *Michael*, *King*, and *Stamps*, and we conclude that a finding in favor of the Greens on any of their alleged state tort law claims would impose additional or different requirements on Collagen, whose product, Zyderm, has already received FDA approval. Such requirements are in conflict with the MDA and thus, the Greens' state law claims are therefore preempted.

In spite of the clear force of preemption in this case, the Greens raise six disparate arguments seeking to overcome federal preemption. We find none of the six arguments persuasive. First, the Greens claim that in the absence of specific MDA/FDA regulations or requirements applicable to Zyderm as a particular device, there is no preemption of state tort law claims. In support of this claim, the Greens cite to 43 Fed. Reg. 18,662 (May 2, 1978). Appellants' Brief at 8. In their brief, the Greens quote a portion of that regulation as follows: "[t]hus from a plain reading of [s]ection [360k] of the Act, it is clear that the scope of preemption is limited to instances where

there are specific FDA requirements applicable to a particular device or *class of devices*. . . . " *Id.* (emphasis added). In this case, the FDA has classified Zyderm as a Class III medical device, which is subject to extensive regulation. Thus, the Greens' claim that there are no specific MDA/FDA regulations pertaining to Zyderm is without merit.

The Greens also maintain that a 1984 FDA advisory opinion letter construing the preemption provision supports their position and should be determinative. An "agency's interpretation of its own statute is controlling so long as [it is] not contrary to Congress' intent." *King*, 983 F.2d at 1134, citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). One purpose of the preemption provision is to encourage manufacturers to engage in research and development of new and improved medical devices and to permit these devices to be marketed with little delay. *Id.* at 1138. Because of the potential chilling effect the FDA advisory opinion letter may have on future research and development, in contravention to Congress' intent, we view the FDA opinion letter as merely advisory and not dispositive.

The Greens also assert that in the absence of divergent state tort law requirements, there is no preemption of state law claims. The court in *Stamps* addressed this issue and rejected the conclusion that the absence of a direct conflict between state and federal regulations compels a finding of no preemption. *Stamps*, 984 F.2d at 1424. The court found support for this result in *Morales v. Trans World Airlines*, ___ U.S. ___, ___, 112 S.Ct. 2031, 2038, 119 L.Ed.2d 157, 169 (1992), which rejected the contention

that express preemption is inappropriate where state and federal law is consistent. *Id.* The *Morales* Court reasoned that such a strained reading of the preemptive provision would create an irrational loophole, and "there is little reason why state impairment of the federal scheme should be deemed acceptable so long as it is effected by the particularized application of a general statute." *Id.* We read *Stamps* and *Morales* as rejecting the proposition that the absence of divergent state law compels a finding of no preemption.

Next, the Greens allege that their state tort law claims are exempt from preemption by express provisions of the MDA. The MDA have an express preemption provision for Pennsylvania which relates to hearing aids; nowhere in that provision are state tort law claims relating to Zyderm even mentioned. 21 C.F.R. § 808.88. State tort law claims involving FDA approved medical devices which are not expressly exempt from preemption are preempted if they impose additional or different requirements.

The Greens also contend that their mislabeling, misbranding and adulterated product claims involve alleged violations of the MDA and are not preempted by the MDA. These claims relate directly to the labeling and packaging of Zyderm, which is regulated by the FDA. *See* 21 U.S.C. §360e(c)(1)(F); *King*, 983 F.2d at 1136. Because a finding against Collagen would require Collagen to make changes in its FDA approved packaging, we conclude that these claims are preempted.

Finally, the Greens argue that because of the reasoning underlying the result in *Cipollone v. Liggett Group, Inc., supra*, their claims for fraud, misrepresentation and

breach of warranty are not preempted. For the following reasons, we disagree:

> [T]he warnings at issue in *Cipollone* were different that those here. In *Cipollone*, the statute required cigarette manufacturers to include a brief health warning in their advertisements; this warning did not affect cigarette advertisements in any other way. The manufacturers were free to make any claims they wished, including express warranties. Here, however, the MDA has imposed much more extensive regulation upon class III device manufacturers. The FDA retains rigid control over the entirety of the labeling and packaging of class III products, largely displacing the ability of manufacturers to make additional claims. This high level of control contrasts with the low level of control in *Cipollone*, and ensures that manufacturers will not be held liable for packaging and labeling imposed by the FDA.

King, 983 F.2d at 1135. Based on the foregoing, we conclude that the MDA preempt the Greens' claims for fraud, misrepresentation and breach of warranty.

Viewing all of the evidence in the light most favorable to the Greens, we are unable to conclude that the trial court committed any error of law in granting summary judgment in favor of Collagen on the basis of federal preemption. Accordingly, we affirm the order entered on September 3, 1993.

Order affirmed.

IN THE COURT OF COMMON PLEAS OF
MONTGOMERY COUNTY, PENNSYLVANIA

IRENE M. GREEN and MARTIN GREEN	:	
vs.	:	NO. 92-07089
RICHARD L. DOLSKY, M.D. and COLLAGEN CORPORATION	:	

OPINION

LOWE, J., November 3, 1993

This is an appeal to The Superior Court of Pennsylvania from this Court's Order of September 3, 1993 granting defendant's Motion for Summary Judgment.

Defendant Collagen Corporation manufactures and distributes Zyderm Collagen Implant (hereinafter Zyderm) which is injected under the skin to improve soft tissue deficiencies. Zyderm is regulated under the Medical Device Amendments of 1976 (hereinafter MDA), 21 U.S.C. §§360c *et seq.* It is classified as a Class III medical device by the Federal Food and Drug Administration (hereinafter FDA) and must therefore be approved by the FDA prior to marketing. In July, 1981 the FDA issued an Order granting Collagen Corporation permission to market Zyderm. This Order was reaffirmed in 1992.

On May 12, 1992 Irene Green filed suit against Richard L. Dolsky, M. D., alleging that on March 17, 1989 he injected her with Zyderm and that as a result thereof she developed an autoimmune disease. On September 3, 1993 this Court granted defendant's Motion for Summary Judgment.

In its Concise Statement appellant raises only the issue of whether this Court erred in holding that plaintiff's state law tort claim is preempted by the MDA.

Plaintiff's state law tort claim is preempted by the MDA. In *Stamps vs. Collagen Corp.*, No. 92-2084 (5th Cir. Feb. 19, 1993) the Fifth Circuit affirmed defendant's Motion for Summary Judgment. Therein the plaintiff claimed to have been injured by collagen injections under state tort law theories of failure to warn, and defective design and manufacture. The Fifth Circuit held that plaintiff's claims were preempted by 21 U.S.C. §360k(a) which provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

In *King vs. Collagen Corp.*, No. 92-1278 (1st Cir., Jan. 15, 1993) the First Circuit held that this provision preempted the plaintiff's claim for damages under state law theories of strict liability in tort; breach of express and implied warranty; negligent design, manufacturing and sale; misbranding; misrepresentation; failure to war [sic]; and fraud.

This Court agrees with the reasonings of these decisions and adopts them as its own.

BY THE COURT:

/s/ Illegible

IN THE COURT OF COMMON PLEAS OF
MONTGOMERY COUNTY, PENNSYLVANIA

IRENE M. GREEN and MARTIN GREEN	:	
vs.	:	NO. 92-07089
COLLAGEN CORPORATION, et al.	:	

ORDER

AND NOW, September 3, 1993, after argument and upon consideration of the briefs of counsel, the Motion for Summary Judgment of defendant Collagen Corporation is hereby granted, and the instant matter is dismissed without prejudice.

BY THE COURT:

/s/ Illegible
J.

Copies this date forwarded to:

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/s/ Illegible

Supreme Court, U.S.
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No. 96-1340

IN THE
Supreme Court of the United States
OCTOBER TERM, 1996

IRENE M. GREEN, *et al.*,
Petitioners,

v.

RICHARD L. DOLSKY and COLLAGEN CORPORATION,
Respondents.

On Petition for Writ of Certiorari to the Supreme Court of Pennsylvania

BRIEF OF COLLAGEN CORPORATION IN RESPONSE TO PETITION

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts common law claims challenging the safety or effectiveness of a medical device that the Food and Drug Administration has found to be safe and effective and has approved for marketing pursuant to the premarket approval process under 21 U.S.C. § 360e(c).*

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* Respondent Collagen Corporation has no parent corporation and no non-wholly owned subsidiaries.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

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Respondents.

On Petition for Writ of Certiorari to the Supreme Court of Pennsylvania

---

BRIEF OF COLLAGEN CORPORATION IN RESPONSE TO PETITION

STATEMENT

1. *Company history and regulatory background.* In the early 1970s, a group of biochemists and physicians at Stanford University developed a purified form of bovine collagen, a natural protein that provides structural support for skin, muscles, tendons, and bones. Together with other investors, they organized respondent Collagen Corporation ("Collagen") to manufacture and distribute collagen products to be used in various medical treatments. The product at issue in this case, Zyderm® Collagen Implant ("Zyderm"), is injected under the skin to correct

or improve soft tissue deficiencies that arise from disease, trauma, or aging.

Zyderm is classified by the Food and Drug Administration ("FDA") as a Class III medical device subject to regulation under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c-360*l*. As this Court has noted,

> Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance," which is known as the "premarket approval," or "PMA" process, is a rigorous one.

Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2246-47 (1996).

The PMA process entails an exhaustive investigation into safety and effectiveness with respect to (1) the persons for whose use the device is intended and (2) the conditions of use prescribed, recommended, or suggested in the labeling of the device. 21 U.S.C. § 360c(a)(2). An applicant who seeks the FDA's approval to market a Class III device must provide:

> (A) full reports of all information, published or known to . . . the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;
>
> (B) a full statement of the components, ingredients, and properties and of the principle or principles of operation of, such device;
>
> (C) a full description of the methods used in, and the facilities and controls used for, the manufacture [and] processing . . . of such device;
>
> (D) . . . adequate information to show that . . . such device fully meets [pertinent] performance standard[s];

> (E) . . . samples of such device . . .;
>
> (F) specimens of the labelling proposed to be used for such device; and
>
> (G) such other information . . . as the [FDA] . . . may require.

21 U.S.C. § 360e(c)(1).

The application for premarket approval also must include, *inter alia,* a "general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended," an "explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device," and a "description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended." 21 C.F.R. § 814.20(b)(3). The application must be periodically updated "with new safety and effectiveness information learned about the device from ongoing or completed studies." 21 C.F.R. § 814.20(e).

A completed application is reviewed by a panel of experts. 21 U.S.C. § 360e(c)(2). After considering the panel's report and recommendation, the FDA will grant the application only if it finds reasonable assurance (1) that the device is safe and effective with respect to both the persons for whose use the device is intended and the conditions of use prescribd, recommended, or suggested in its labeling, (2) that the manufacturing and processing methods and facilities are satisfactory, and (3) that the proposed labeling is not false or misleading in any manner. 21 U.S.C. §§ 360c(a)(2) and 360e(d)(2); *see also* 21 C.F.R. § 814.44.

Collagen filed an application with the FDA for premarket approval of Zyderm on April 30, 1980. Its application included, *inter alia,* the results of clinical testing

in over five thousand human subjects. R. 48b, 67b-91b ("R." refers to the record in the court below). Following more than one year of detailed investigation, the FDA found Zyderm to be safe and effective and approved it for marketing. 46 Fed. Reg. 46394 (1981). The FDA's approval order for Zyderm set forth numerous "conditions of approval," including the following:

> *Before making any change that may affect the safety or effectiveness* of the device, [Collagen must] submit a supplemental PMA for review and approval by FDA. Such changes include, but are not limited to:
>
> (1) new indications for use;
>
> (2) labeling changes;
>
> (3) changes in manufacturing facilities, methods or quality control procedures, and involvement of new subcontractors, suppliers, or distributors;
>
> (4) changes in sterilization procedures;
>
> (5) changes in packaging;
>
> (6) changes in the performance or design specifications, circuits, parts, components, accessories, ingredients, or physical layout of the device.

R. 452b-456b. Since 1981, Collagen has marketed Zyderm as a prescription-only medical device pursuant to the authority granted by the FDA in this approval order. In 1991, the FDA reviewed Zyderm's record and reconfirmed its initial finding of safety and effectiveness. R. 42b-43b.

2. *Proceedings in this case.* In March 1989, petitioner Irene Green was treated with Zyderm by her physician, respondent Richard Dolsky. Pet. App. 33. In May 1992, she and her husband brought suit against Dolsky and Collagen in the Court of Common Pleas of Montgomery County, Pennsylvania, claiming that the treatment had caused an autoimmune disorder. *Id.* Relief was sought

under state tort law theories of negligence, strict liability, breach of warranty, and fraud. *Id.* at 19.

Collagen moved for summary judgment on the ground that petitioners' tort claims were barred by the MDA pre-emption statute, 21 U.S.C. § 360k(a). That statute bars states from imposing, with respect to a medical device, "any requirement—(1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." The trial court granted Collagen's motion, holding that petitioners' claims were barred for the reasons stated in *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied,* 114 S. Ct. 86 (1993), and *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied,* 114 S. Ct. 84 (1993). Pet. App. 33-34.

The Superior Court of Pennsylvania affirmed. Pet. App. 32. The court explained:

> a finding in favor of the Greens on any of their alleged state tort law claims would impose additional or different requirements on Collagen, whose product, Zyderm, has already received FDA approval. Such requirements are in conflict with the MDA and thus, the Greens' state law claims are therefore preempted.

Id. at 29. In reaching this conclusion, the Court considered and rejected petitioners' "six disparate arguments seeking to overcome federal preemption." *Id.*

Following this Court's decision in *Lohr,* the Supreme Court of Pennsylvania reversed and remanded for further proceedings. Pet. App. 15. The court noted that *Lohr* "has resolved at least some of the questions involved in this case." *Id.* at 7. But the court also noted that *Lohr* "is not wholly applicable" because it involved a medical device that had been approved for marketing under 21 U.S.C. § 360e(b)(1)(B) (the "§ 510(k) notification

process") as substantially equivalent to a device already on the market and thus, unlike Zyderm, had not been subject to an investigation into safety and effectiveness. *Id.* at 10.

The court concluded that petitioners' claims of negligent development, failure to warn, and mislabeling were "impermissible because they attempt to substitute a reasonableness analysis characteristic of negligence claims for the judgment of the FDA in approving the development and distribution of this particular product in the course of its premarket approval process." *Id.* at 12. Similarly, the court determined that petitioners' claims of strict liability and breach of warranty also were contrary to the FDA's findings of safety and effectiveness and sought the imposition of state requirements different from or in addition to those imposed by the FDA. *Id.* at 14. On the other hand, the court held that petitioners' various claims to the effect that Collagen had "fraudulently completed the premarket approval process," *id.* at 13 n.7, or had failed to monitor patients treated with Zyderm, were not preempted because such claims "in essence, mirror FDA requirements." *Id.* at 12; *see also id.* at 14 n.8. The court further concluded that petitioners' claims against Dr. Dolsky "are permissible medical malpractice claims." *Id.* at 15.

DISCUSSION

A careful inquiry into safety and effectiveness is the hallmark of the FDA's "rigorous PMA process." *Lohr*, 116 S. Ct. at 2247. The Pennsylvania Supreme Court held that once the FDA has approved a medical device pursuant to the PMA process, 21 U.S.C. § 360k(a) bars common law causes of action that, in effect, ask a jury to second-guess the FDA's own determination of safety and effectiveness. That holding is both correct and fully consistent with *Lohr*.

This Court nonetheless may wish to grant plenary review. The case affords the Court an opportunity to decide,

once and for all, the proper scope of the MDA preemption statute as applied to medical devices that the FDA has found to be safe and effective and has approved for marketing pursuant to the PMA process. The question is one of substantial importance, and it arises with great frequency. Moreover, as petitioners note, the decision below directly conflicts with at least one post-*Lohr* decision by a state court of last resort, *Fiore v. Collagen Corp.*, 1996 WL 343648 (Ariz. App. 1996), *appeal denied* (Ariz. Jan. 14, 1997). *See* Pet. 13. Collagen therefore acquiesces in petitioners' request that their petition be granted.

If the petition is granted, the Court also should grant Collagen's conditional cross-petition. The petition and cross-petition, taken together, will enable the Court to consider MDA preemption in the context of the full range of claims commonly asserted in cases of this sort.

I. THE MDA PREEMPTS COMMON LAW CLAIMS CHALLENGING THE SAFETY AND EFFECTIVENESS OF MEDICAL DEVICES THAT THE FDA HAS APPROVED FOR MARKETING PURSUANT TO THE PMA PROCESS

The medical device at issue in *Lohr* had not been scrutinized for safety and effectiveness pursuant to the PMA process. Instead, the device had been cleared for marketing pursuant to the § 510(k) notification process upon a determination that it was substantially equivalent to a device already on the market. The case presented two broad questions: first, whether state law tort claims impose "requirements," within the meaning of 21 U.S.C. § 360k(a), that are potentially subject to preemption; and second, if so, whether the § 510(k) notification process imposes federal "requirements," also within the meaning of the statute, sufficient to preempt such claims. *See Lohr*, 116 S. Ct. at 2259 (Breyer, J., concurring).

A majority of the Court in *Lohr* determined that common law causes of action do impose "requirements"

within the meaning of 21 U.S.C. § 360k(a) and thus may be subject to preemption. *Lohr*, 116 S. Ct. 2262-63 (O'Connor, J., concurring and dissenting) ("the term 'requirement' encompasses state common-law causes of action"); *id.* at 2259-60 (Breyer, J., concurring) ("the MDA will sometimes pre-empt a state-law tort suit"). The court below correctly adopted this construction of the MDA preemption statute. See Pet. App. 9-11.

This Court laid the foundation for its consideration of the second general question in *Lohr*, concerning the nature of the particular federal requirements there at issue, by contrasting the truncated § 510(k) notification process with the far more elaborate PMA process involved in this case:

> [Under the PMA process, m]anufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission. . . .
>
> . . . The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours. As one commentator noted, '[t]he attraction of substantial equivalence to manufacturers is clear. [Section] 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.'

Lohr, 116 S. Ct. (citations omitted). Consequently, the court reasoned, the manufacturer's claim of preemption in *Lohr* "exaggerates the importance of the § 510(k) process." *Id.* at 2254.

The § 510(k) notification process " 'is focused on *equivalence*, not safety.' " *Lohr*, 116 S. Ct. at 2254 (emphasis in original). A device approved for marketing

pursuant to that process "has never been formally reviewed under the MDA for safety or efficacy." *Id.* The Court therefore determined that requiring "the manufacturer of the device . . . to defend itself against state-law claims of negligent design" would not interfere with the federal regulatory scheme. *Id.* at 2255; *see also id.* at 2263-64 (O'Connor, J., concurring and dissenting) ("Because the § 510(k) process seeks merely to establish whether a pre-1976 device and a post-1976 device are equivalent, and places no 'requirements' on a device, the Lohrs' defective design claim is not preempted"). The Court further determined that, as applied to a device approved for marketing pursuant to the § 510(k) notification process, "general federal regulations governing the labeling and manufacture of all medical devices," *id.* at 2256, are insufficiently specific to have preemptive effect standing on their own:

> [T]he[se] federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements.

Id. at 2258.

The decision below is consistent with this analysis. In *Lohr,* this Court drew support from the FDA's determination that state and local regulations are preempted when the agency "has established specific counterpart regulations or there are other specific requirements applicable to a particular device." 21 C.F.R. § 808.1(d). *See Lohr,* 116 S. Ct. at 2257. The FDA itself has explained that for Class III medical devices like Zyderm, "the counterpart FDA requirement [is] that the product have premarket approval." 43 Fed. Reg. 18661, 18664 (1978). In addition, as the facts of this case demonstrate, the marketing approval order generated by the PMA process imposes numerous specific requirements applicable to the particular device.

A PMA approval order represents a license to market the approved medical device strictly in accordance with the conditions specified by the FDA to ensure safety and effectiveness. By regulation, "[a] device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80. In other words, the specifications in a PMA application become, upon approval, binding federal requirements. This means, as the court below recognized, that Collagen, in producing and selling Zyderm, must adhere to all the specifications in its PMA application relating to indications for use, proposed labeling, manufacturing methods and facilities, sterilization procedures, packaging, ingredients, and performance and design. Pet. App. 11. *See also, e.g., King*, 984 F.2d at 1134 ("it is clear that the FDA has imposed requirements on Zyderm relating to labeling, design, manufacturing and other aspects of the device"). Under 21 U.S.C. § 360k (a), these detailed and device-specific requirements have preemptive effect.

In concluding that such federal requirements give rise to preemption, the court below was in good company. Virtually every federal court of appeals that has considered the issue has held that the comprehensive PMA process, together with the detailed conditions imposed on a manufacturer as a result of that process, constitute specific requirements that have preemptive effect under 21 U.S.C. § 360k(a). *See, e.g., Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995) (PMA procedures impose "specific requirements applicable to a particular device under the act"); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995) ("The premarket approval process is a specific requirement for a device within the meaning of 21 U.S.C. § 360k(a)"); *Stamps*, 984 F.2d at 1421-22 & n.3, 1424 & n.8; *Mitchell*

v. Collagen Corp., 67 F.3d 1268, 1279 (7th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2576 (1966); *contra, Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 2579 (1996).

Claims based upon theories of strict liability, negligence, mislabeling, failure to warn, express and implied warranty, and so forth, are all, at bottom, claims that the medical device was not safe and effective and should have been designed, manufactured, packaged, labeled, or sold in a manner different from that both explicitly approved by the FDA upon finding the device safe and effective and explicitly required by the FDA as a condition of continued marketing. The central purpose of the MDA preemption statute is to protect manufacturers like Collagen from conflicting demands of this sort. That statute does not permit the FDA's painstakingly meticulous PMA process, and the detailed and comprehensive requirements that the FDA imposes as a result of that process, to be supplanted by the notoriously unscientific process of trial by jury. *See* Pet. App. 12.

II. THE QUESTION PRESENTED IS RECURRENT AND IMPORTANT

This Court granted certiorari in *Lohr* because the federal courts of appeals were in conflict concerning whether the § 510(k) notification process creates preemptive "requirements" within the meaning of 21 U.S.C. § 360k(a). *Lohr*, 116 S. Ct. at 2250 n.6. That conflict was resolved by *Lohr*. But as the decision below and the ruling of the Arizona Supreme Court in *Fiore* demonstrate, the lower courts are unlikely to achieve unanimity in applying the precepts of *Lohr* to cases involving the very different PMA process.

Before the decision in *Lohr*, the First, Third, Fifth, Seventh, and Eighth Circuits all had held that the requirements imposed by the FDA pursuant to the PMA process

are preemptive. *See* pages 10-11, *supra*. Only the Ninth Circuit in *Kennedy* had reached the contrary result. Although the issue currently is pending before the Seventh Circuit on remand in *Mitchell*, no federal court of appeals has yet decided this issue in light of *Lohr*. However, in the closely related context of the investigational device exemption ("IDE") under 21 U.S.C. § 360j(g), the Sixth Circuit recently held that the MDA preemption statute bars common law claims of the kind asserted by petitioners here. *Martin v. Telectronics Pacing Systems, Inc.*, 1997 WL 35041 (6th Cir. Jan. 31, 1997). This indicates that the existing circuit conflict with respect to the PMA process will not simply fade away.

To say that the issue is recurrent, moreover, would be a considerable understatement. The issue arises whenever a tort claim is filed against the manufacturer of a medical device that the FDA has found to be safe and effective. Collagen alone has been forced to litigate the scope of MDA preemption in no less than four federal courts of appeals (*King* (1st Cir.); *Stamps* (5th Cir.); *Mitchell* (7th Cir.); and *Kennedy* (9th Cir.)) and additionally in four state courts of last resort (this case (Penn.); *Fiore* (Ariz.); *Mears v. Marshall*, 324 Or. 130, 921 P.2d 966 (1996); and *Worthy v. Collagen Corp.*, 921 S.W.2d 711 (Tex. App.-Dallas 1995), *writ granted*, 40 Tex. Sup. Ct. J. 94 (Nov. 15, 1996)). This repetitive litigation has been burdensome for Collagen and for the courts as well. Other manufacturers of medical devices, and other federal and state courts, face the same problem.

Petitioners' suggestion that there should be a summary disposition of this case, Pet. 14-15, is not responsible. Because of the wide differences between the PMA process and the § 510(k) notification process, this case cannot be decided solely on the basis of a rote application of *Lohr*. This case nonetheless is a suitable vehicle for the resolution of the scope of MDA preemption in cases involving medical devices found to be safe and effective

and approved for marketing pursuant to the PMA process. In view of the unquestioned importance and recurrent nature of the question presented, it would be appropriate for the Court to grant plenary review in order to decide that question in this case.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

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